DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 15, 2015

CSA Medical Incorporated
Ms. Sherrie Coval-Goldsmith
Vice President Regulatory Affairs/Quality Assurance
91 Hartwell Avenue
Lexington, Massachusetts 02142

Re: K143625
Trade/Device Name: truFreeze® System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: December 22, 2014
Received: December 24, 2014

Dear Ms. Coval-Goldsmith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment C – Indications for Use Statement

510(k) Number (if known): K143625

Device Name:
truFreeze® System

Indications For Use:
The truFreeze® System is intended for cryogenic destruction of tissue requiring either active or passive venting during surgical procedures.

The truFreeze® System is Indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign and malignant lesions.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

csamedical.com

CSA Medical Inc.
91 Hartwell Avenue
Lexington, MA 02421
781.538.4720 tel
781.538.4730 fax

K143625

510K Summary
TruFreeze® System

Applicant	CSA Medical
Establishment Registration Number	3004534508
Contact Person	Sherrie Coval-Goldsmith VP RA/QA CSA Medical 91 Hartwell Ave Lexington, Ma 02142 Phone: 781-538-7447 Fax: 781-538-4730 sgoldsmith@csamedical.com
Summary Date	June 9, 2014
Proprietary Name	truFreeze® System
Classification	Class II
Classification Name	Cryosurgical Unit, Cryogenic Surgical Device
Regulation Number	21 CFR 878.4350
Classification	Product Code GEH
Predicate Device	K133258 (truFreeze System)

Device Description

The truFreeze system is a cryosurgical tool that applies medical-grade liquid nitrogen to the treatment area via a small, low pressure, open tipped catheter. The truFreeze System consists of (1) a console and (2) a disposable spray kit.

Console:
The console is the central interface of the system and is comprised of a touch panel computer (TPC) and cryogen, suction and electronics modules packaged in a mobile cart. Users interact with the console through a dual foot pedal and a touch panel. An off-the-shelf controller and associated software manage the cryogen level sensing, filling, pressure, cooling, defrost, suction, timing and data management functions. A wireless remote control provides alternative timer control from a distance in the treatment room. A fill kit, stored on the rear of the console, allows for liquid nitrogen transfer from the source tank to the console. Safety features include indicators, tank pressure relief valves, an isolated low voltage power system, and an emergency button to be used in the event of user or technical malfunction.

Disposable spray kit:

The truFreeze disposable spray kit consists of 5 individually packaged sterile single-use catheters (7 Fr Straight Tip Catheter and one Catheter Introducer.) and 5 individually packaged cryogen decompression tubes (CDTs) (each containing one Dual Lumen 20 Fr CryoDecompression Tube (CDT), Connector, and Suction Tubing.). The catheter is flexible and capable of retroflex in a scope. The CDT and accessory tubes are included for use with the on-board suction system.

Labeling (Intended Use/Indications for Use and Instructions for Use Document)

The truFreeze System is identical in its Intended Use as the predicate device (K133258 truFreeze system). Both devices describe the ablation of benign and malignant tissue in general terms and the requirement to use either active or passive venting during surgical procedures. Both devices are indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign and malignant lesions. The proposed modification adds the word "System" after the truFreeze name to add clarity to the name of the device.

The truFreeze System is intended for cryogenic destruction of tissue requiring either active or passive venting during surgical procedures.

The truFreeze System is indicated for use as a cryosurgical tool in the fields of dermatology, gynecology, and general surgery, to ablate benign and malignant lesions.

The Instructions for Use document did not contain the same information regarding RFID tag use as the Operator's manual and did not contain the same information regarding the physician having complete control of the procedure through activation of the foot pedal as contained in the Operator's manual. These modifications ensure consistency in content between the Instructions for Use document and Operator's manual.

The Instructions for Use document provide additional notes to the physician to assign a health care professional, in the procedure room, to audibly notify the physician of the timer display. This provides a redundant safe guard to the system's built in audible beep associated with the timer display. The intent of this addition is to enhance safe use of the device.

Therefore, the revised intended use/indications for use statement and revised Instructions for Use document raise no new issues of safety or effectiveness.

Technical and Operational Characteristics

The truFreeze System is identical in design, hardware and software, as well as operational and technological characteristics as the predicate device and supports that no new safety concerns are being raised by changes to the Instructions for use document and thus raises no new issues of safety or effectiveness.

Testing

The truFreeze System was previously subjected to a comprehensive test program that included electrical safety and electromagnetic compatibility testing, software testing, animal testing, biocompatibility and sterilization testing. Since the change does not involve any changes to the hardware or software of the truFreeze system, no additional testing was conducted to support demonstration of substantial equivalence in performance of the truFreeze system to its predicate device.

Rationale For Substantial Equivalence

The labeling (inclusive of Intended Use/Indications for Use statement and Instructions for Use document) as well as the technological characteristics of the truFreeze System and the predicate device (K133258 truFreeze system) were compared. The Intended Use/Indications for Use statement of the two devices had identical general claims and do not raise new questions of safety and performance. The proposed changes to the Instructions for Use (IFU) document ensure consistency between the IFU and the system Operator Manual and enhance the safe use of the device by assigning a health care professional in the procedure room to audibly notify the physician of the timer display. This provides a redundant safe guard to the system's built in audible beep associated with the timer display.

Conclusion

Based on the comparison of label, technology and testing comparisons, the truFreeze device is substantially equivalent to the predicate device listed above.